Pulse Oximeter

Operation Manual

Preface

For this manual, the issued Date is October 2005 (Version: 1.5).

Safety Symbols

⚠ **Warning**

A **Warning** indicates that failure to follow proper instructions can cause death or injury to the patient, the operator, or serious damage to the equipment.

⚠ **Caution**

A **Caution** indicates that failure to follow proper instructions may cause serious injury to the patient, the operator, or may cause damage to the equipment.

⚠ **Note**

A **Note** is an indication of supplemental information to the operation, or handling, of the equipment, or associated accessories.

This symbol indicates type BF applied part according to IEC 60601-1.

This symbol indicates the dual-purpose socket can connect with the PC communication cable.

Illustrations

All illustrations in this manual are provided as examples only. They may not necessarily reflect your setup or data displayed on your Pulse Oximeter.

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Chapter 1 Safety Information

This chapter contains important safety information related to general use of the Pulse Oximeter. Other important safety information appears throughout the manual in sections that relate specifically to the precautionary information.

⚠ **Note**

- Important! Before use, carefully read this manual, all safety information and specifications.
- This device is not intended for home use.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- The Pulse Oximeter complies with Class-A requirements of the EN55011 standard.

⚠ **Warning**

- This device is not intended as a device used for treatment purposes.
- It is important for the hospital or organization that uses this equipment to carry out a reasonable maintenance schedule. Failure to do so may result in equipment failure, or injury to the patient or operators.
- The Pulse Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

⚠ **Warning**

- The Pulse Oximeter is to be operated only by medical doctors or trained healthcare personnel to measure the SpO_2 of clinical patients (including adult, pediatric and neonatal patients) in hospitals and healthcare agencies or in the process of transporting patients.
- The Pulse Oximeter is designed for real-time and rapid measurement of the patient's SpO_2. It is not suitable for long-time continuous patient monitoring. Continual measurement must not exceed 2 hours.
- Before using the Pulse Oximeter, the user should check and make sure the device and its accessories can work properly and safely.
- When using the Pulse Oximeter together with the electrical surgery equipment, the user should pay attention to and guarantee safety of the patient being measured.
- To avoid fire or explosion hazards, do not use the Pulse Oximeter at places where such flammable material as anesthesia gas is present.
- Do not pull or lift the Pulse Oximeter by its connection cable. That may lead to device falling and consequent patient injuries.
- It is not recommended to hang the Pulse Oximeter when transporting patients. Safety hazards may arise from the large amplitude swing during the transportation.
- Do not use the Pulse Oximeter or its sensor around working MRI equipment. Induction current may lead to damages. The device may affect operation of MRI equipment and vice versa.
- The Pulse Oximeter and its accessories may be contaminated by microorganism during transporting, use and storage. Use the

recommended methods to sterilize and disinfect the Pulse Oximeter or its accessories when the packing material is damaged, or it has not been used for a long time.

⚠ **Caution**

- The Pulse Oximeter should be appropriately placed. Keep it from falling, strong vibration or other mechanical damage.
- The Pulse Oximeter is a commonly sealed device. The user should keep its surface dry and clean, and prevent any liquid from infiltrating it.
- Don’t use mobile phones around when the Pulse Oximeter is in operation.
- The Pulse Oximeter should only be maintained by personnel approved by our company.
- Before use the Pulse Oximeter on patients, the user should be familiar with its operation.

FOR YOUR NOTES

Chapter 2 General

2.1 Introduction

The Pulse Oximeter is a portable measuring device powered by common or rechargeable batteries. It is compact, light, flexible to use and easy to learn.

Parameters measured by the Pulse Oximeter include: arterial oxygen saturation (SpO_2), pulse rate (PR) and pulse strength. The Pulse Oximeter measures these parameters through a SpO_2 sensor and displays them on the LCD screen after certain further processing.

The Pulse Oximeter is operated and controlled by three buttons, which are Power button, Backlight button and Confirm ID button. The Pulse Oximeter is also capable of managing measured data and transmitting the patient's trend through the dual-purpose socket to a PC for printing.

2.2 Functions

The Pulse Oximeter has the following functions:

- Measuring: SpO_2, PR and pulse strength;
- Prompting: Memory full, ID full, low battery, standby, and technical error etc.
- Power managing: automatic standby, automatic shutdown;
- Data Managing: data storage, data protection, data deletion;
- Data Printing: patient information and trend data;

For the data printing function, you must install the Pulse Oximeter management system in a PC equipped with a printer, and connect the Pulse Oximeter with the PC by a communication cable.

2.3 Appearance

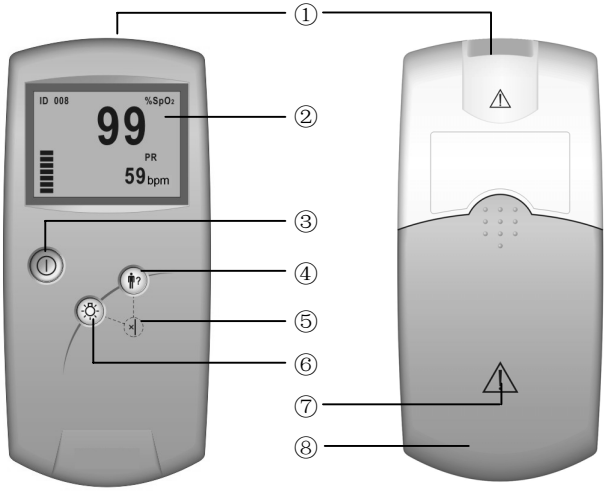


Figure 2-1 Front Panel

Figure 2-2 Back Panel

Table 2-1 Appearance description

No.	Description	Remarks
①	Dual-purpose socket	It connects SpO2 sensor or PC communication cable.
②	LCD	It displays information listed in Table 2-2.
③	Power	It turns on or off the device.
④	Confirm ID	It confirms the patient ID for current measurement.
⑤	Delete ID	A key combination of ④ and ⑥.
⑥	Backlight	It turns on or off the backlight.
⑦	⚠	Caution. Refer to this manual.
⑧	Battery door	Open it to install or remove batteries.

2.4 Displayed Information

Figure 2-3 shows information displayed on the LCD screen.

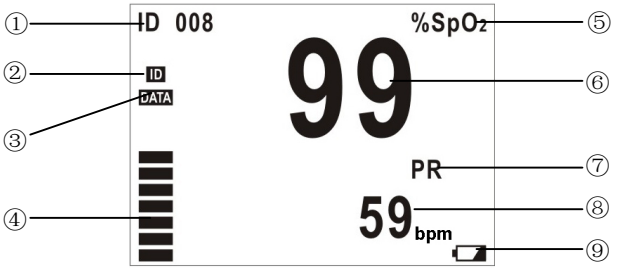


Figure 2-3 Displayed Information

Table 2-2 Description of displayed information

No.	Description	Remarks
①	ID number	It displays current ID number ranging from 000 to 100
②	ID Full	It appears when ID≥95 and blinks when stored ID is being covered by new ID.
③	Memory Full	It appears when previous data is to be covered by new data. Please refer to **5.1.1 Data Storage**.
④	Pulse Strength	It can display 7 segments at most to indicate real time pulse strength.
⑤	%SpO_2	It displays "%SpO_2".
⑥	SpO_2 value	It displays SpO_2 value and is refreshed every second.
⑦	PR	It displays "PR".
⑧	PR value	It displays PR value and is refreshed every second. Unit: bpm (beats per minute)
⑨	Low battery	It appears only when the battery energy is low.

Please refer to **Chapter 3 Installation** for displayed information of startup and standby modes.

2.5 Button Operation

Three soft buttons are available on the front panel.

Power Backlight Confirm ID

Figure 2-4 Buttons

2.5.1 Power Button

Power-on: Press to turn on the device.

Power-off: Press and hold for two seconds to turn off the device.

⚠ **Note**

- The Pulse Oximeter is powered by batteries only. Please install batteries before use according to the descriptions in **3.2 Install Batteries**.
- In case the SpO_2 cable becomes disconnected or the finger moves away from the sensor, the Pulse Oximeter will automatically enter the standby mode. Under this mode, when a finger is inserted into the sensor, the Pulse Oximeter will automatically resume the operation mode. Otherwise, if no finger is inserted in 5 minutes, the Pulse Oximeter will be automatically shut down.

2.5.2 Backlight Button

Backlight on: Press the Backlight button to turn on backlight.

Backlight off: Press the Backlight button to turn off backlight.

2.5.3 Confirm ID Button

The Confirm ID button is used to add data. It enables the user to add data, without using a new ID number, to a re-test for the same patient after the sensor is accidentally disconnected.

Refer to section **5.1 Data Management** for detailed use of this button.

2.5.4 Delete ID Button

The Delete ID button is a key combination of the Backlight button and the Confirm ID button.

Refer to section **5.1 Data Management** for detail use of this button.

FOR YOUR NOTES

Chapter 3 Installation

3.1 Unpacking and Inspection

Please carefully remove the Pulse Oximeter and its accessories from the package and check items by comparing them to the packing list.

- Check the device for any mechanical damages.
- Check all cables and accessories for damage.

In case of any problem, please contact our Customer Service.

⚠ **Note**

- Please save all packaging materials for future transportation or storage use.

⚠ **Warning**

- The user should keep the packing materials at places out of children's reach. Before disposing the packing materials, check with your local waste officials for details in your area for recycling options or proper disposal.

3.2 Install Batteries

The Pulse Oximeter is powered by four batteries. Follow the steps below to install batteries before use:

1. Hold the Pulse Oximeter in one hand.
2. Place the other hand on the battery cover.
3. Push the cover away as Figure 3-1 shows.
4. Place batteries into the slots per the "+" and "-" indications as

shown in Figure 3-2.

5. Push back the battery cover.

⚠ **Note**

- Before disposing of the battery, check with your local solid waste officials for details in your area for recycling options or proper disposal.

⚠ **Caution**

- Please use AA alkaline batteries or rechargeable batteries. Do not use carbon or poor quality batteries. Remove the batteries if the device is not to be used for a long time.
- During use, replace batteries of insufficient energy in time with good ones; abnormal power supply may lead to product damages or even personnel injuries.

Figure 3-1 Install battery 1

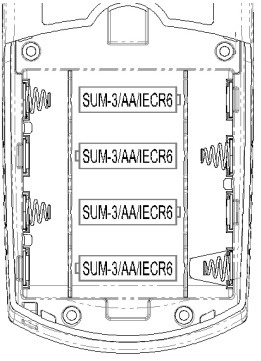


Figure 3-2 Install battery 2

3.3 Power-on

Press the Power button to turn on the Pulse Oximeter. The startup interfaces and version information will be displayed, and then the initialization interface as shown in Figure 3-3. After that, the Pulse Oximeter will automatically switch to the standby mode as shown in Figure 3-4.

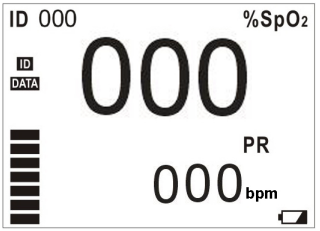


Figure 3-3 Startup interface 3

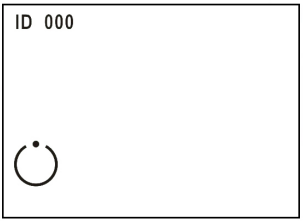


Figure 3-4 Standby interface

3.4 Connect SpO_2 Sensor

As the Figure 3-5 shows, you can connect the SpO_2 sensor to the Pulse Oximeter by simply inserting the sensor's connector to the dual-purpose socket.

Figure 3-5 Connect SpO_2 sensor

3.5 Connect Computer

The Pulse Oximeter can be connected to a Personal Computer through a communication cable to transmit patient's trend to the computer for printing.

Simply connecting one end of the PC communication cable to the dual-purpose socket and the other end to the PC's serial port.

This symbol will be display in the LCD screen indicating that the Pulse Oximeter has connected with the PC successfully.

Chapter 4 Measurement

4.1 Measuring Principle

The Pulse Oximeter is capable of measuring SpO_2, PR and pulse strength.

The Pulse Oximeter measures SpO_2 by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side. The amount of light transmitted is determined by multiple factors, most of which are fixed. The blood flow in arteries is one of the factors that change with time, because it is pulsating.

Usually, the wavelength of the light transmitted by a red-light LED can be detected by the sensor is 660nm, and by an infrared LED is 940nm. Maximum power output of the LED is 4mW.

The Pulse Oximeter measures the absorbed light during the pulsatile period to acquire pulse rate and pulse strength as well as arterial oxygen saturation, and then after a further processing, displays the results on the LCD screen. The displayed SpO_2 value is of functional saturation.

4.2 Precautions

⚠ **Note**

- Do not perform SpO_2 monitoring and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO_2 value.
- It is recommended that each measurement last longer than 15 seconds. Otherwise, if the SpO_2 sensor falls off during the measuring process, new data can't be added to the same patient.
- The Pulse Oximeter is not recommended for prolonged monitoring.

⚠ **Warning**

- Check the SpO_2 sensor and its cable for damages before use. Do not use damaged parts.
- Don't use the Pulse Oximeter to measure patients whose pulse rate is lower than 25bpm, which may cause incorrect results.
- Remove the SpO_2 sensor from the patient after measurement.
- As with any medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation. Cables of electrical surgical equipment should not be winded around that of the SpO_2 sensor.
- Do not put the sensor on extremities with arterial catheter or venous syringe.
- If no pulse is found or the reading is unreasonable, first check the patient's condition, and then refer to qualified engineer to check the device and the SpO_2 sensor for proper functions.
- Do not reuse disposable SpO_2 sensors.

⚠ **Warning**

- Prolonged and continuous monitoring may increase the risk of burns at the site of the sensor. If you have to use the Pulse Oximeter for Prolonged and continuous monitoring, it is especially important to check the sensor placement, and ensure proper attachment on neonates and patients of poor perfusion or skin sensitive to light. Check the sensor location every 2~3 hours and move to another location if the skin deteriorates.
- Make sure no contamination or scar exists in the site where the sensor is placed. Otherwise, the measured result may be incorrect because the signal received by the sensor is affected.
- When used on different patients, the Pulse Oximeter is prone to crossed contamination, which should be prevented and controlled by the user. Disinfection is recommended before using the SpO_2 sensor on other patients.

4.3 Measuring Steps

The measurement is usually done using the adult finger SpO_2 sensor. Palm or foot sensors may be adopted for infants. Before measurement, check the SpO_2 sensor and its cable for damages. Do not use the sensors if any damage is found.

4.3.1 Adult Measurement

Please follow the steps below to use the adult finger SpO_2 sensor:

1. Insert the sensor's connector to the dual-purpose socket.
2. Turn on the Pulse Oximeter to enter the standby mode.
3. Attach the sensor to an appropriate site on the patient.

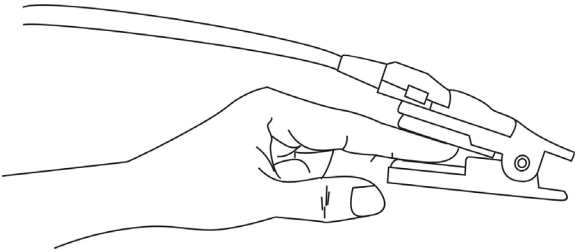


Figure 4-1 How to place the adult SpO_2 sensor

4. The readings will be displayed on the LCD screen a moment later.

⚠ **Note**

- During measurement, make sure that the light window is over the fingernail, and the cable should be on the backside of the hand.
- To acquire accurate results, please read data until the sensor is steadily placed.
- Readings may not be accurate when either the sensor or the patient is moving.

4.3.2 Neonatal Measurement

Please follow the steps below to use the neonatal SpO_2 sensor:

1. Insert the SpO_2 sensor‘s connector into the dual-purpose socket.
2. Turn on the Pulse Oximeter to enter the standby mode.
3. Appropriately place the neonatal SpO_2 sensor (refer to **4.3.3 Placing Neonatal SpO_2 Sensor**).
4. The readings will be displayed on the LCD screen a moment later.

4.3.3 Placing Neonatal SpO_2 Sensor

Neonate SpO_2 sensor consists of a Y-shape SpO_2 sensor and its sheath. Insert t he LED and PD ends of the Y-shape SpO_2 sensor respectively into the upper and lower grooves on the sheath (Figure 4-2). The figure 4-3 shows us the neonate SpO_2 sensor after insertion.

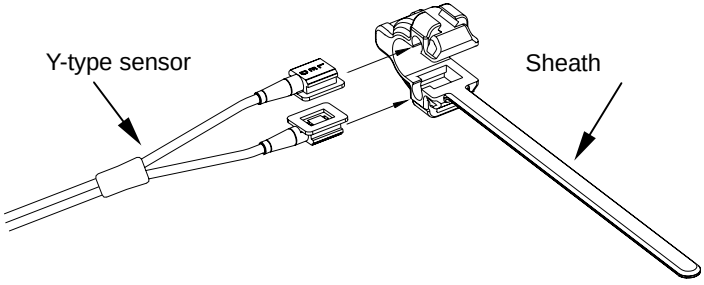


Figure 4-2 Placing Neonatal SpO_2 Sensor 1

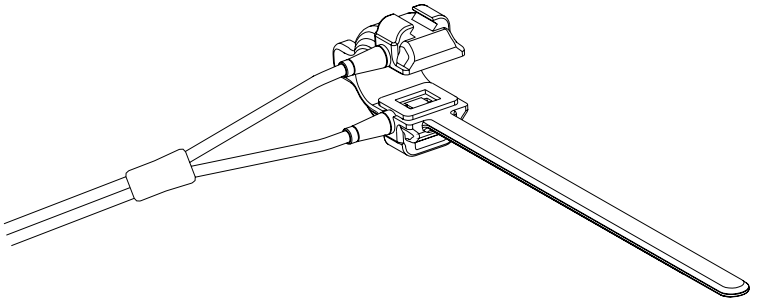


Figure 4-3 Placing Neonatal SpO_2 Sensor 2

Wind the SpO_2 sensor around a hand or foot of a neonate patient. Hold the sensor, pull the belt and fit one of its sides with “V” edge into the “V” groove on the corresponding side of the sheath. Appropriately elongate the belt to about 20mm, and fit the “V” edge of the other side of the belt into the “V” groove of the other side of the sheath. Then, loosen the belt. After the “V” edges of the two sides of the belt fit well into the “V” grooves on the two sides of the sheath, put the belt into the first lock bar to fasten the belt. See figure 4-4. If the belt is too long, you may put it into the second lock bar. You must position the SpO_2 sensor in this way so as to make the photoelectric component face the correct position. Besides, note not to elongate the belt too much, which may lead to inaccurate measurement and block the blood circulation severely.

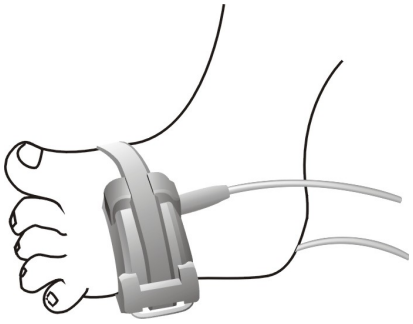


Figure 4-4 Placing Neonatal SpO_2 Sensor 3

4.4 Measuring Restrictions

If the accuracy of any measurement seems unreasonable, first check the patient's vital signs by an alternate method, and then check the device for proper function.

Inaccurate measurements may be caused by the following reasons.

- Incorrect sensor application or use;
- Significant levels of dysfunctional hemoglobins (e.g., carboxyhemoglobin or methemoglobin);
- Intravascular dyes such as indocyanine green or methylene blue;
- Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material);
- Venous pulsations;
- Excessive patient movement;

- Placement of a sensor on the same extremity with a blood pressure cuff, arterial catheter, or intravascular line.

Loss of pulse signal can occur in the following situation:

- The sensor is too tight;
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight;
- A blood pressure cuff is inflated on the same extremity as the one with a SpO_2 sensor attached;
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
- There is arterial occlusion proximal to the sensor;
- The patient is in cardiac arrest or in shock.

Chapter 5 Other Functions

5.1 Data Management

5.1.1 Data Storage

The Pulse Oximeter has its internal memory to store data. The memory is divided into the ID Data Zone and Trend Data Zone.

The ID Data Zone is capable of storing 100 patients' ID data at most. When the number exceeds 100, new data will automatically cover the old one from the earliest stored data.

ID001 data	ID002 data	ID003 data	·····	ID100 data

One ID data include:

- Number of the SpO_2 and pulse rate values stored to this ID,
- Maximum SPO_2 value of this ID,
- Minimum SPO_2 value of this ID,
- Average SPO_2 value of this ID,
- Maximum PR value of this ID,
- Minimum PR value of this ID,
- Average PR value of this ID.

Trend Data Zone is capable of storing 200 trend data (TD, as shown below) at most. When the number exceeds 200, new data will automatically cover the old data from the earliest stored data.

TD 001	TD 002	TD 003	·····	TD 200

The first trend data will be stored 15 seconds after the pulse is found. Thereafter one trend data will be stored every 2 minutes. One trend data includes:

- Average SpO_2 value within the 2 minutes.
- Average PR value within the 2 minutes.

⚠ **Note**

- The first trend data are the instant values of SpO_2 and PR.
- For a patient, his (her) ID data are calculated from all measured trend data of him (her).
- Once the trend data of a patient is covered, all trend data of that patient will be deleted, however, the ID data will not be deleted.

5.1.2 Data Adding

The previously stored ID number appears on the screen when a finger is inserted into the SpO_2 sensor. It will keep blinking for 8 seconds after the pulse is found.

- Press the Confirm ID button before the ID number stops blinking, the Pulse Oximeter will set the ID number as current patient ID. The data measured thereafter will be superadded to the previous ID.
- If the user doesn't press the Confirm ID button before the ID number stops blinking, a new ID number, which is the blinking number plus 1, will be set as the current patient ID.

The Confirm ID button is of no use when the current ID number is 000, which will automatically change to 001 when the pulse is found.

5.1.3 Data Protection

The Pulse Oximeter has data protection function. When the power is turned off accidentally during the process of storing a data, the Pulse Oximeter will evaluate completeness of the last stored data when it is restarted. If the data is complete, it will be validated, otherwise it will be invalidated.

5.1.4 Data Deletion

Press the Delete ID button in the standby mode, the message “DELETE ALL?” will be displayed as shown in figure 5-1.

Figure 5-1 Delete data1

Figure 5-2 Delete data2

- To delete all stored data:

Press the Delete ID button again. As shown in figure 5-2, the message “ALL DELETED” will be displayed for 2 seconds. Then the Pulse Oximeter will switch back to the previous standby mode, the ID number restores to “000”, symbols of memory full as well as ID Full disappears.

- Not to delete all stored data:

Don’t press the Delete ID button and wait for 10 seconds, the “DELETE ALL?” message will disappear automatically and the previous operation will be cancelled. The Pulse Oximeter will switch back to the previous mode.

5.2 Messages Prompting

The Pulse Oximeter can display various prompt messages. In table 5-1, prompt messages as well as their causes and solutions are listed.

Table 5-1 Table of Indications

Message	**Cause**	**Solution**
“Low Battery”	Batteries energy lower than 4.0 Voltage.	Replace batteries in time
“Memory Full”	The internal memory is almost full.	Stored data is to be covered. Export data in time.
Blinking “Memory Full”	Memory is full.	Stored data is being covered. Export data in time.
“ID Full”	ID number Stored is greater than 95.	ID data is to be covered. Export data in time.
Blinking “ID Full”	ID data is being covered.	Export data in time.
“Standby”	The device is in standby mode.	None.
“Communication”	The device is in communication mode.	None.
DELETE ALL?	The Delete ID button is pressed.	Refer to **5.1.4 Data Deletion**
ALL DELETED	The Delete ID button is pressed again after “DELETE ALL?” appears.	None.

The Pulse Oximeter can also display technical error messages. In table 5-2, error messages as well as their causes and solutions are listed.

If the LCD screen can't display anything, it may be damaged or error occurs during system self-test. Please shut down the device (if can't, remove the batteries) and contact our Customer Service.

Table 5-2 Error indications

Error Message	**Cause**	**Solution**
Initiate Error	Failed self-test	Shut down the device (if can't, remove the batteries) and contact us for service.
Please Release the Button	Button error	Check for jammed button. If problem remains, contact us for service.
Pulse Not Found Searching…	Pulse not found	Check the patient and alert the doctor.

5.3 Power Management

Battery Detection

The Pulse Oximeter can detect the battery energy and

- display "Low Battery" message when battery voltage is less than 4.0 V;
- shut down the device automatically when battery voltage is less than 3.85V.

Energy Saving

The Pulse Oximeter can save the energy of the batteries by

- switching to the standby mode automatically when the finger disconnects from the sensor or the sensor disconnects from the Pulse Oximeter.
- shutting down automatically if no finger is inserted into the sensor within 5 minutes under the standby mode.

⚠ **Note**

- The Pulse Oximeter will automatically switch from the standby mode to the normal operation mode when a finger is inserted into the sensor.

⚠ **Note**

- Please refer to **Chapter 7 Pulse Oximeter Management System** to learn more functions if your Pulse Oximeter has been provided with PMS software.

Chapter 6 Maintenance

6.1 System Check

Before using the Pulse Oximeter, perform the following steps.

- Check for any mechanic damages.
- Check for all cables and accessories for damage.
- Check all functions of the Pulse Oximeter to make sure the Pulse Oximeter is in proper working condition.

If any damage, malfunction or potential safety hazard is found, stop using the Pulse Oximeter on patients. Contact the biomedicine engineers of the hospital or our Customer Service immediately.

The overall check of the Pulse Oximeter, including function and safety check, should be performed by qualified personnel every 6-12 months (depending on the policy of your institution), and each time after maintenance.

Any check involving opening the back plate should be performed by qualified maintenance personnel only. Function and safety check can also be performed by service personnel of our company.

⚠ **Warning**

- Failure to follow a satisfactory maintenance schedule may cause injury to the patient, operator or cause serious damage to the device.

6.2 General Cleaning

The Pulse Oximeter must be kept dust-free. Regular cleaning (depending on the policy of your institution) of its exterior surface and LCD screen is strongly recommended. First absorb non-corrosive detergent with clean and soft cloth or cotton ball. Manually twist the cloth or cotton ball to a proper degree and then use the dried cloth or cotton ball for cleaning.

⚠ **Warning**

- Before cleaning the Pulse Oximeter or its associated cables or sensors, make sure the Pulse Oximeter is turned off and the batteries are taken out.

Optional detergents are:

- Clean Water
- Soapy Water
- Medical Alcohol
- Diluted Ammonia Water
- Diluted Sodium Hypochlorite（Bleaching agent）
- Diluted Formaldehyde 35 to 37%
- Hydrogen Peroxide 3%
- Ethanol
- Isopropanol

⚠ **Note**

- The diluted sodium hypochlorite from 500ppm（1:100 diluted domestic bleaching powder）to 5000ppm（1:10 diluted domestic beaching powder）is very effective. This concentration depends on

the amount of organisms (blood or mucus) on the surface to be cleaned.

⚠ **Caution**

- Do not use ammonia-based or acetone-based cleaners such as acetone.
- Most detergents must be diluted before use. Please follow the manufacturer's directions carefully.
- Do not use abrasive material, such as steel wool.
- Do not allow any liquid inside the device. Do not immerse the device into any liquid.
- Do not leave any residual detergent on any part of the device. Always wipe them off with a clean, soft cloth or cotton ball. Do not expose the device to environment with strong sunlight or high temperature.
- If the device is contaminated by chemical products, please clean the polluted device with proper methods. Contact the biomedicine engineers of the hospital or our Customer Service.

Absorb certain amount of medical alcohol with dry and soft cloth or cotton ball to clean the SpO_2 sensor's surface, LED and photodetector and then wipe them dry with dry cloth or cotton ball.

The cleaning solutions recommended above are for general cleaning only. Our company is not reliable to any results if the user applies them to control contagious diseases. Please consult medical professionals in contagious disease for information.

6.3 Sterilization/Disinfection

Sterilization or disinfection may, to a certain degree, damage the Pulse Oximeter and SpO_2 sensor. It is not recommended unless stipulated as necessary in the Hospital Maintenance Schedule. Cleaning is recommended before sterilization or disinfection.

Recommended disinfection materials: ethylate, and acetaldehyde.

The SpO_2 cable can be cleaned with 3% hydrogen peroxide solution or 70% isopropanol solution. Active reagents are also effective for this purpose. Do not immerse the cable connector into the above-mentioned solutions.

⚠ **Caution**

- Dilute the solution per manufacture instructions or adopt concentration as low as possible.
- Clear of the device's surface of residual solution immediately with wet cloth.
- Do not use EtO or formaldehyde for this purpose.
- Do not sterilize or disinfect the device under high pressure or high temperature.

6.4 Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect or decontaminate the device appropriately before disposing of it in accordance with your country's law for equipment containing electrical and electronic parts. For SpO_2 sensor, follow local regulations regarding disposal of hospital waste.

Chapter 7 Pulse Oximeter Management System

The Pulse Oximeter Management System software (PMS software) is developed to realize more functions of the Pulse Oximeter. The PMS software runs in Windows 98/2000/XP operation system. In conjunction with the internal software of the Pulse Oximeter, the following functions can be realized.

- Outputting data and upgrading internal software.
- Previewing data exported
- Adding patient information
- Printing patient data

7.1 Installation and Uninstall

7.1.1 Installation

Before you use PMS software, you must first install it in your PC. Take Windows 2000 for example, you can follow the steps below for installation.

1. Insert the installation CD into the CD-ROM.
2. Run the file “Setup.exe” in the installation CD.

3. Choose your favorite language according to the prompt. Click “OK”,

and then click “Next” in the next dialog box.

4. Input the correct serial number, and click “Next” to resume.
5. Select the serial port to connect the Pulse Oximeter with your PC, and click “Next” to resume.
6. Choose the destination folder where the PMS software is to be installed.
7. Click “Next” and “Finish” according to the prompt.
8. After the installation is completed, a new shortcut icon will appear in the desktop of your computer as shown below.

9. Double click the icon to run the PMS software.

7.1.2 Uninstall

To uninstall the PMS software, please follow the steps:

1. Click “Start-Setting-Control Panel”, and double click the icon for “Add/Remove Programs” to open the “Add/Remove Programs” dialogue box.
2. Select the “Pulse Oximeter Management System”, and click the “Change/Remove” button. Then following the prompt to uninstall the PMS software.

⚠ **Note**

- The steps above are provided as examples only. They maybe a bit different from your operation if you use other operation system.

7.2 Main Interface

Double clicking the shortcut icon for PMS software on the desktop of your computer, the Main Interface of PMS software will be displayed as shown below.

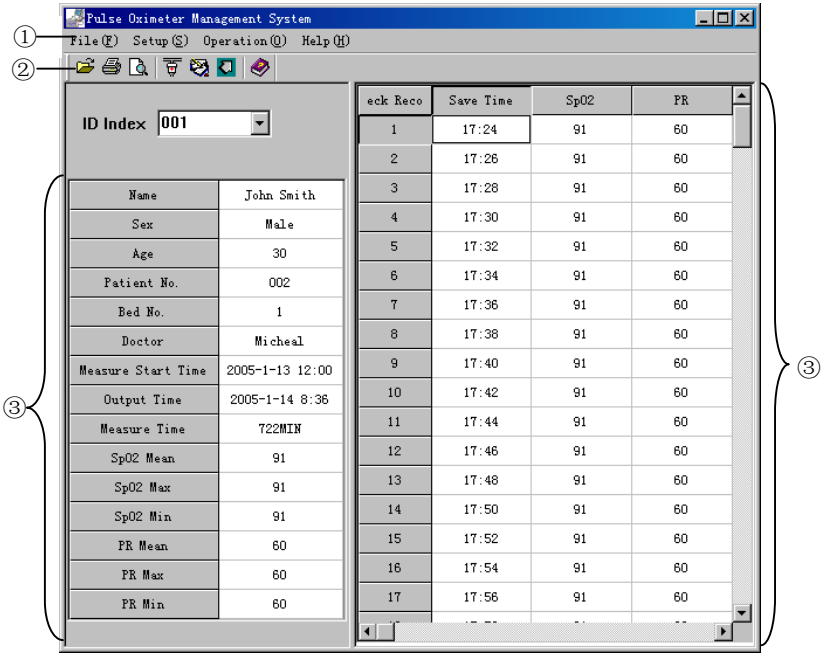


Figure 7-1 Main Interface

① Menu Bar ② Tool Bar ③ Data Area

7.2.1 Menu Bar

In the Menu Bar, four menus are available: <File>, <Setup>, <Operation> and <Help>. See the descriptions below to know the details.

<File>

Click the <File> menu to see its pull-down menu as shown in Figure 7-2. There are five submenus:

- <File Management>: Click to open the “File Management” dialogue box.
- <Print>: Click to print the current patient data.
- <Print Preview>: Click to preview the data to be printed.
- <Print Setting>: Click to open the “Print Setting” dialog box.
- <Exit>: Click to exit the PMS software.

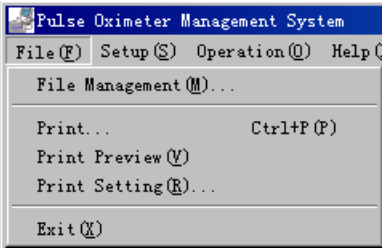


Figure 7-2 File Menu

<Setup>

Click the <Setup> menu to see its pull-down menu as shown in Figure 7-3. There are two submenus:

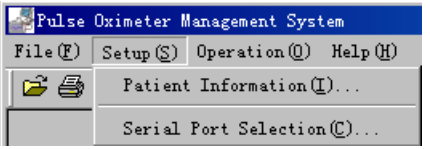
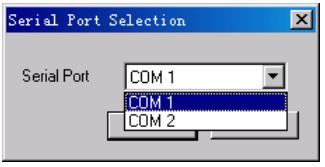


Figure 7-3 Setting Menu

- <Patient Information>: Click to open the “Modify Patient Information” dialogue box.
- <Serial Port Selection>: Click to open the “Serial Port Selection” dialogue box.



When you use the Data Output or Software Upgrade function, the default serial port might have been occupied. At this time, you can click the <Serial Port Selection> menu to select other serial port.

<Operation>

Click the <Operation> menu to see its pull-down menu as shown below. There are two submenus:

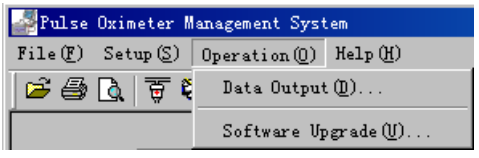


Figure 7-4 Operation Menu

- <Data Output>: Click to conduct the “Data Output” function.
- <Software Upgrade>: Click to open the “Input Password” dialogue box.

<Help>

Click the <Help> menu to see its pull-down menu as shown below.

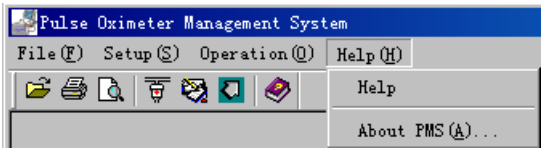


Figure 7-5 Help Menu

- <Help>: Click to open the “Help” document.
- <About PMS>: Click to show the copyright information.

Note

- When you open the “Help” document, if a dialog box pops up and informs you to install language pack, please select “Never install any language packs”, and then click “Cancel” button.

7.2.2 Tool Bar

In the tool bar, you can see the following shortcut icons.

Table 7-1 Shortcut Icons

Icon	Icon Name	Description
	File Management	Equals to <File Management> submenu
	Print	Equals to <Print> submenu
	Print Preview	Equals to <Print Preview> submenu
	Serial Port Selection	Equals to <Serial Port Selection> submenu
	Patient Information	Equals to <Patient Information> submenu
	Data Output	Equals to <Data Output> submenu
	Help	Equals to <Help> submenu

7.2.3 Data Area

The Data Area displays the data of the current ID. The left part of Data Area is Information Area, and the right part is Patient Data Area.

- Information Area

It displays the patient Name, Sex, Age, and Doctor etc.

- Patient Data Area

It displays the value of the measured SpO_2 and PR as well as the corresponding Index No and Save Time of each measurement.

The content in the Information Area can't be directly inputted or changed. Please select <Patient Information> under the <Setup> menu, or click the shortcut icon.

⚠ **Note**

- The data displayed as "---" is invalid.
- The "(ADD)" appearing beside the check record number is to indicate that the data thereafter are additional ones to this ID.

7.3 Functions

Before operate the function hereinafter, please first connect the Pulse Oximeter with your PC (Refer to **3.4 Connect Computer**), and then double click the shortcut icon on the desktop to run the PMS software.

7.3.1 Data Output

PMS software can output the data stored in the Pulse Oximeter into the hard disk of your PC.

1. Select <Data Output> under the <Operation> menu to start data outputting as shown in Figure 7-6. During outputting, you can click exit to cancel the operation.

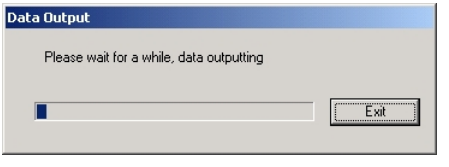


Figure 7-6 Data Outputting

2. When data outputting is finished, the “Save As” dialog box will pop up as shown below.

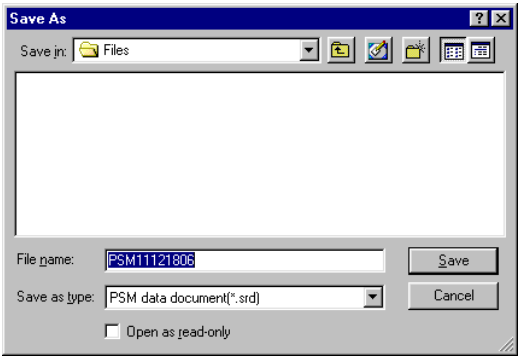


Figure 7-7 Save the Outputted File

3. You can choose the file directory where the data is to be stored, and change the file name.
   - The default file directory is the “Files” folder under the directory where the PMS software is installed.
   - The default file name is “PMS********.srd”, where the “********” represents the current system time. For example, “11091133“ means November 9th, 11 o’clock and 33 minute. The hour is 24-hour format.
4. Click “Save” button to save the data. Meanwhile, information and data outputted will be displayed in the Data Area.
5. If error occurs during outputting, the following prompt will pop up.

ERROR
Communication error, communication interrupt.
Check whether serial port line is connected correctly, whether serial port setup is correct.
OK

Figure 7-8 Communication Error

When this situation occurs, please check whether the serial port is correctly connected, and try to select another serial port by clicking the <Serial Port Selection> menu.

7.3.2 Software Upgrade

With the PMS software, you can upgrade the internal software of Pulse Oximeter.

1. Click <Software Upgrade> under the <Operation> menu, the “Input Password” dialogue box will pop up.

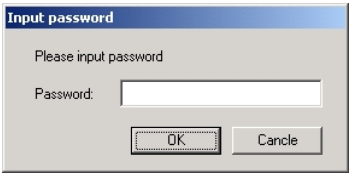


Figure 7-9 Input password

2. Input the correct password, and then click the OK button. The “Software Upgrade” dialog box will pop up as shown in Figure 7-10.

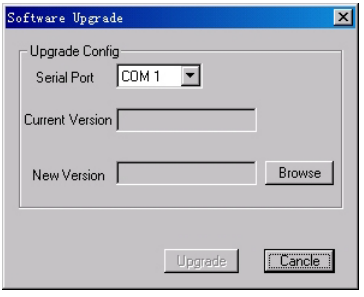


Figure 7-10 Software Upgrade

3. Select the serial port and click “Browse” to display the dialogue box as shown in Figure 7-11.

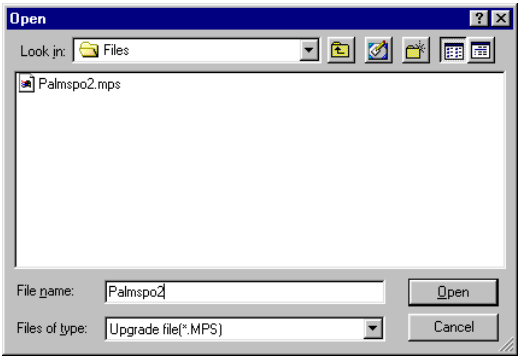


Figure 7-11 Open Upgrade File

4. Select the Upgrade File and click the “Open” button.
5. The version of the Upgrade File will be displayed in the figure 7-10.
6. Click the “Upgrade” button, the system will check the validity and verify version of the Upgrade File. If the Upgrade File is valid, and the current version loaded on the Pulse Oximeter is lower than the Upgrade file, the following message will be displayed.

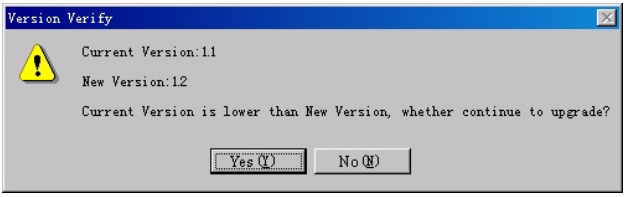


Figure 7-12 Version Verify

7. Click “Yes”, and the system will start to upgrade the software automatically (Figure 7-13). If you click "Cancel" when the upgrading is in process, the software in the Pulse Oximeter will be damaged. You need to upgrade the software again.

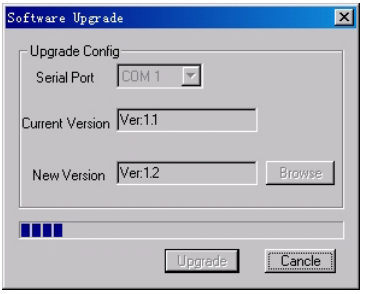


Figure 7-13 Software Upgrade

If the version of Upgrade File is lower or the same as that loaded on the Pulse Oximeter, corresponding different message will be displayed in Figure 7-12. Click “Yes” to continue to upgrade, and “Cancel” to cancel upgrading.

If the Upgrade File is invalid, the following message will be displayed.

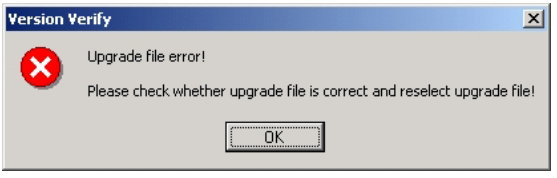


Figure 7-14 Upgrade File Error

8. Click “OK” to finish the upgrading.

Figure 7-15 Upgrade Succeed

7.3.3 File Management

File management function helps you to open or delete the data outputted conveniently.

1. Click <File Management> from the <File> menu, the “File Management” dialogue box will pop up as shown in Figure 7-16.

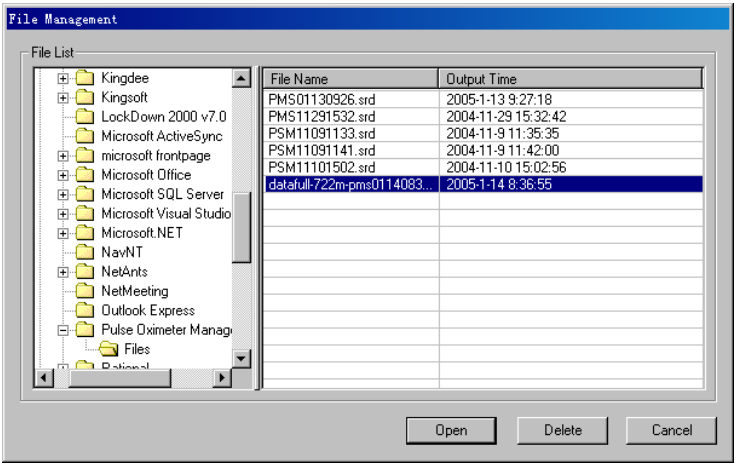


Figure 7-16 File Management

2. You can choose the folder where the outputted data is saved in the File List. The Files contained in that folder will be displayed in the right.
3. To open a file, choose a file name and click “Open” button, and then the data contained in the file will be displayed in the Data Area of the Main Interface.
4. To delete a file, choose a file name and click “Delete” button, and then the selected file will be deleted. The data of all patients contained in this file will be deleted. You can’t delete the data of one patient ID contained in the file.

7.3.4 Modify Patient Information

1. Click <Patient Information> from the <Setup> menu, the “Modify Patient Information” dialog box will pop up as shown in Figure 7-17.

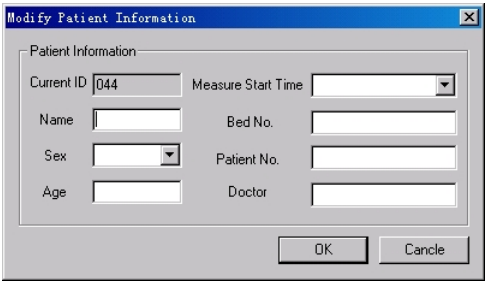


Figure 7-17 Modify Patient Information

2. You can input the following information:
   - Name: 30 characters at maximum.
   - Sex: Male of Female.
   - Age: The age of the patient.
   - Measure Start Time: The displayed format of the time is dependent on the setting of the PC’s system. For example, 2004/9/12/15:30, here the hour is 24-hour format.
   - Bed No.: Range from 1to 65535.
   - Patient No.: 12 characters (English Character or number) at maximum.
   - Doctor: Name of the doctor, 30characters at maximum.
3. Click “OK”, the dialog box will disappear, and the information inputted will be displayed in the Information Area.
4. Click ”Cancel”, the dialogue box disappears and no information listed above will be modified.

7.3.5 Print Data

1. Click <Print Setting> from the <File> menu to display the “Print Setting” dialogue box. You can set the print range of the patient ID.

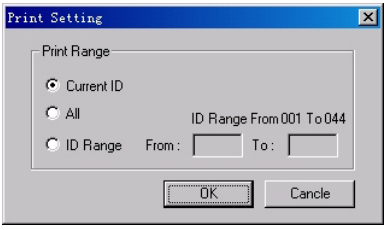


Figure 7-18 Print Range

2. Click “OK” and set the properties according to the printer your personal computer installed in the pop-up dialog box.
3. Click “OK” to start printing the selected ID data.
4. Before printing, you can select <Print Preview> from the <File> menu to preview the content to be printed, as shown in Figure 7-19.

ID001

Name	ABC	Sex	Male
Age	30	Patient No.	100
Bed No.	1	Doctor	ABC

Measure Start Time		Output Time	2004/11/10/09:13	Measure Time	868MIN
SpO2 Mean	99	SpO2 Max	100	SpO2 Min	62
PR Mean	89	PR Max	90	PR Min	66

Check Record	Save Time	SpO2	PR
1	+07:52	99	89
2	+07:54	99	89
3	+07:56	99	89
4	+07:58	99	89

Figure 7-19 Print Preview

5. You can also click <Print> from the <File> menu, and click <OK> button in the pop-up dialogue box to start printing.

7.3.6 Prompt Message

Table 7-2 Prompt Message

Error Message	Cause	Solution
Communication Error, communication interrupt	The connection between the Pulse Oximeter and PC is interrupted.	Restart the Pulse Oximeter, and check the connection between Pulse Oximeter and PC.
Upgrade File Error	The upgrade file is invalid	Check the right upgrade file is selected and conduct the upgrade again.
Password Error	The password inputted is incorrect.	Input the correct password or exit the upgrade operation.
Serial Port Error	Other program is using the serial port selected.	Choose another serial port or close the program that using the selected serial port.
Age Input Error	The age inputted is out of the range: 1 to 255.	Input the age again
Bed No Input Error	The No. inputted is out of the range:1 to 65535	Input the Bed Number again
Measure Start Time and Output Time are unconformity	The inputted Measure Start Time adds the total measured time is later than the Output Time.	Input the Measure Start Time again.
File not found	The file name you inputted is not available under the current directory.	Select file again
ID Range Error	The inputted ID range is wrong	Input the ID Range again.

FOR YOUR NOTES

Chapter 8 Accessories

The following SpO_2 sensors are recommended for the Pulse Oximeter Pulse Oximeter.

Table 8-1 Order information

Product	**PN**
518A multi-site SpO_2 sensor	518A-30-90226
512B finger SpO_2 sensor	512B-30-90134
512D finger SpO_2 sensor	512D-30-90200
512E finger SpO_2 sensor	512E-30-90390
512G Soft SpO_2 Sensor, Pediatric, Finger	512G-30-90607
DS-100A Adult Oxygen sensor	9000-10-05161
OXI-P/I paediatric/infant sensor	9000-10-07308
OXI-A/N adult/neonatal sensor and sensor wraps	9000-10-07336
Disposable SpO_2 sensor for adults	0010-10-12333
Disposable SpO_2 sensor for pediatrics	0010-10-12334
Disposable SpO_2 sensor for infants	0010-10-12335
Disposable SpO_2 sensor for neonates	0010-10-12336
Adult oxygen sensor (>30Kg)	0010-10-12202
Pediatric oxygen sensor (10~50Kg)	0010-10-12203
Infant oxygen sensor (3~20Kg)	0010-10-12204
Neonate/Adult oxygen sensor (<3Kg or >40Kg)	0010-10-12205
Small SpO_2 ear sensor (ES-3212-9)	0010-10-12392

⚠ **Caution**

- Using other accessories may cause damage to the device.

Appendix A Specifications

Classification	
Item	**Description**
Electroshock proof type:	Type IIb device according to the 93/42EEC directive.
Anti-electroshock type:	Powered by internal batteries.
Anti-electroshock degree:	Type BF
Harmful liquid proof degree:	IPX0. Ordinary sealed equipment without liquid proof function
Disinfection /Sterilization:	Refer to **Chapter 6 Maintenance**
Working mode:	Continuous
Basic specifications	
Item	**Description**
To be used on:	Adult, pediatric and neonatal patients
Measured parameters:	SpO_2 PR Pulse strength.
Signal interface:	Dual-purpose interface for both SpO2 sensor and PC communication
Display:	Matrix LCD
Display area:	Not less than 42mm×35mm.
Back light:	Blue

Dimension:	65mm×140mm×32mm
Weight:	About 130g（not including battery and SpO2 sensor）

Functions

Item	**Description**
Indications:	Memory Full ID Full Low battery Standby Technical error
Power saving features:	Automatic standby/shutdown
Printing:	Printer: The PC's printer Paper: A4 Content: ID data and trend data
Downloading:	Download new software revision through PC serial port.

Ambient environment

Item	**Description**
Temperature range:	Operation: 0°C to 50°C Transportation and storage: -20°C to 60°C
Relative humidity:	Operation: 15% to 95%（no condensing） Transportation and storage: 10% to 95%（no condensing）
Barometric:	Operation: 86KPa to 106KPa Transportation and storage: 50KPa to 106KPa

Electrical specifications	
Item	**Description**
Working voltage:	4.0 to 6.4 VDC
Power supply:	Batteries
Battery specifications:	Common 1.5V AA alkaline or rechargeable batteries
Shutdown leakage current:	< 200uA
Battery run time:	15-hour continuous operation with alkaline batteries.
Power Consumption	720mW
SpO_2&PR specifications	
Item	**Item**
SpO_2 range:	0% to 100%
SpO_2 resolution:	1%
SpO_2accuracy:	70% to 100%:±2% (Adult, Pediatric) 70% to 100%:±3% (Neonate) 0% to 69%: No specified.
PR range:	25 to 254bpm
PR resolution:	1bpm
PR accuracy:	±2bpm

P/N: 0850-20-30761